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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,606	04/11/2005	Michael Vajdy	PP18892.003	9598

27476 7590 05/29/2008  
NOVARTIS VACCINES AND DIAGNOSTICS INC.  
INTELLECTUAL PROPERTY R338  
P.O. BOX 8097  
Emeryville, CA 94662-8097

EXAMINER
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SNYDER, STUART

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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05/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

<b>Application No.</b> 10/501,606	<b>Applicant(s)</b> VAJDY ET AL.	
<b>Examiner</b> STUART W. SNYDER	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 08 February 2008.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-6, 8, 14-16, 19-23, 27-29, 32 and 34-36 is/are pending in the application.  
4a) Of the above claim(s) 3, 19-23 and 27-29 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-2, 4-6, 8, 14-16, 32 and 34-36 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \*    c)  None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Amendment of claims 1 and 19 and cancellation of claims 7, 9-13, 17-18, 24-26, 30-31, 33 and 37-40 in Applicants' filing of 2/8/2008 is acknowledged. Claims 1-2, 4-10, 12-16, 32 and 34-36 are pending and examined herein; claims 3, 19-23, and 27-29 are provisionally withdrawn from examination.

This application contains claims 3, 19-23, and 27-29, drawn to an invention nonelected with traverse in the reply filed on 7/5/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Objections***

2. Objection to claim 34 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is moot and withdrawn in view of cancellation of the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 4-10, 12-16, 32 and 34-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Vajdy, Keefer, Kumar, Hanes, Kang, Tobery, Vogel and Cease. Applicant's arguments filed 2/8/2008 have been fully

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considered but they are not persuasive. Applicants argue that the combination of HIV env and tat antigens with an E. coli LT is not obvious in view of the primary reference and that none of the secondary references cures this alleged defect. Applicants further argue that the rarity of Tat-specific CTL epitopes teaches away from using Tat in a CTL immunogenic composition.

Currently, there is no effective anti-HIV vaccine. Furthermore, there is no consensus concerning correlates of immunity; *i.e.*, although survival of HIV infected person's correlates, in part, with the so-called peak and set point viral loads during the initial acute phase of infection, it is not clear how to achieve such results given the remarkable plasticity of the HIV genome and its rapid response to immune pressure. Other successful viral vaccines include attenuated virions that establish low-level, non-pathogenic infections such as the polio and smallpox vaccines. The success of such an approach has been proposed to be a robust B- and T-cell response. A comparable situation in the HIV field have been the *nef*-deleted SIV vaccines that in most cases are sufficient to establish protection to challenge but in some cases result in a pathogenic and deadly SIV infections in primate models (see, for example, Ruprecht, 1999). Such vaccines include as much of the virion as possible primarily because it is not known parts what may be necessary for an effective vaccine. Furthermore, several vaccine strategies have been based on preparing 5' and 3' portions of the HIV-genome in vaccinia vectors used in DNA/vaccinia prime-boost strategies to achieve a persistent and lasting T-cell and B-cell response. These strategies have proven

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promising but ultimately not successful when challenged with a heterologous virus. Finally, many workers have purposely included tat genes in attenuated vaccinia in multi-valent vaccine candidates (see, especially, Hel, et al., 2002) for the specific purpose of broadening the anti-SIV immune response and in contrast to the work of Cease, et al., have seen an enhancement of the immunoproliferative in response to the vaccine. Thus, a skilled vaccinologist at the time of filing of the instant Application would have found it obvious to include tat as well as env in a multivalent vaccine candidate in combination with the LT-based adjuvants.

Rejection of claims 1-2, 4-10, 12-16, 32 and 34-36 under 35 U.S.C. 103(a) as being unpatentable over the combination of Vajdy, Keefer, Kumar, Hanes, Kang, Tobery, Vogel and Cease is **maintained**.

#### ***Conclusion***

4. No claims are allowed.
5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory

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period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Mary E Mosher, Ph.D./  
Primary Examiner, Art Unit 1648

Stuart W Snyder  
Examiner  
Art Unit 1648

SWS